Serial No.: 10/628,692
Art Unit: 1651

REMARKS

Disposition of Claims

Upon entry of the foregoing amendments, claims 1-14 and 19 will remain pending in the application and stand ready for further action on the merits. Claims 15-18 have been canceled, as being drawn to a non-elected invention, in response to a previous restriction requirement made by the Examiner. These claims have been canceled without waiver of the subject matter claimed therein and Applicants reserve the right to file a divisional application containing these claims.

In addition, claim 1 has been amended herein to clarify that the particulate may be derived from natural bone-derived material which is described at Paragraph [0023] of the Specification.

The concentration of gel component is clearly defined in amended claim 1 as discussed throughout the Specification, particularly at Paragraphs [0028] to [0030].

In claim 5, the term, "carrier material" has been amended to read - - - carrier gel - - - which has sufficient antecedent basis.

Claims 7, 13, and 14 have been amended to clarify that the bone repair material further comprises at least one P-15 polypeptide sequence of collagen. This amendment is fully supported by the Specification, particularly at Paragraphs [0010]; [0019]; and [0025]. Referring to Bhatnagar, US Patent 5,635,482, the disclosure of which is incorporated by reference in the present application, the composition of the P-15 polypeptide sequences is clearly described at column 4, lines 14-18.

Claim 8 has been amended to delete the objected to phrase. The concentration of the hyaluronic acid gel is clearly provided as being in an amount of about 25-70 weight percent.

Claims 9, 10, and 11 have been amended so they are now dependent upon claim 8.

In claim 12, the term, "bone repair graft material" has been amended to read - - - bone repair material - - -. Each of claims 9-12, as amended, has proper antecedent basis.

In addition, claims 13 and 14 have been amended to clarify that the bone repair material of claims 8 and 3 (respectively) further comprise at least one of a P-15 polypeptide sequence of collagen.

Finally, claim 19 has been amended so there proper antecedent basis and correct a typographical error.

In view of these amendments, applicants believe that claims 1-14 and 19 meet each of the requirements under 35 U.S.C. §112 and respectfully ask that this rejection be withdrawn.

Claim Rejections under 35 U.S.C. §102

The Office Action rejects claims 1 and 3-5 under 35 U.S.C. §102(b) as being anticipated by Gertzman, US Patent 6,030,635 ("Gertzman"). It is submitted that the presently claimed invention, as recited in amended claims 1 and 3-5, is not anticipated over the disclosure in Gertzman for the reasons discussed below.

Applicants agree with the Examiner that Gertzman discloses a malleable putty that is applied to bone defect sites for promoting new growth at the site. As the Examiner points out, the putty comprises a mixture of demineralized, osteogenic bone powder having a particle size in the range of about 100 to about 850 microns in a carrier solution comprising a high molecular weight carrier in water. Suitable carriers are described as being selected from hyaluronic acid, chitosan, dextran, and the pluronic block copolymers of polyethylene oxide and polypropylene oxide having a molecular weight in the range of

500,000 to 3,000,000 Daltons. The composition contains about 25 to about 40% bone powder (Abstract).

However, as opposed to the putty material described in Gertzman, the bone repair putty of the present invention comprises a substantially greater amount of bone particulate. Particularly, as recited in the above amended claims, the bone particulate is present in Applicants' composition in an amount of at least about 50% by weight. This high concentration of bone particulate is important, because it helps promote more bone formation as discussed at Paragraph [0026]. The bone particulate provides a natural scaffold for bone regeneration. Furthermore, even at these relatively high concentrations, Applicants' composition has good viscosity and handling properties. This allows a clinician to mold and shape the material to the desired structure at the bone repair site. The putty has good dimensional stability and maintains the high level of particulate in suspension. The bone particulate is not allowed to migrate away from the bone repair site and this enhances new bone growth. In contrast, when the amount of bone particulate in prior art formulations is increased to 50% concentration or greater, the putty tends to dry out and it becomes grainy as described in Paragraph [0030] in the present Specification.

This is confirmed by the disclosure and working examples in Gertzman. Putty formulations having a bone powder concentration of 50% by weight show poor formability properties according to Gertzman. (See Examples II, III, XII, and XIII.) These compositions are difficult to mold and shape into the proper configuration for the bone repair site. Rather, Gertzman teaches that the bone powder should be at a concentration of 25 to 35% by weight and preferably 30 to 35% by weight. (See claim 1 at column 10, lines 63-65; column 5, lines 23-26; and Examples I [30%] and VIII [33%] which are described as being the best embodiments of the putty at column 4, line 53.)

As the Examiner recognizes, a claim is anticipated under 35 U.S.C. §102(b) only if each and every element of the claim is found in a single prior art reference. It is respectfully submitted that amended claims 1 and 3-5 are not anticipated by Gertzman,

because there is no disclosure or suggestion in Gertzman for a bone repair putty having good handling properties, wherein the putty has a bone particulate concentration of at least 50% by weight.

Concerning the disclosure in Gertzman for a composition comprising hyaluronic acid and a concentration up to 75% by weight of bone particles at column 5, lines 57-61, it is respectfully submitted that this refers to a sponge sheet or mat of bone which is cut to shape by the dental surgeon. A sponge sheet or mat has a completely different structure and form than a putty material which is molded and shaped by hand to fit the geometry of the bone repair site. Gertzman clearly distinguishes between the different forms of material: malleable putty compositions, flowable gels, and sponge sheets and mats. As discussed above, Gertzman explicitly teaches away from the present invention asserting that putty materials containing bone powder at concentrations of 50% have poor molding and handling properties.

In view of the foregoing, it is respectfully requested that the rejection of claims 1 and 3-5 under 35 U.S.C. §102(b) in view of Gertzman be withdrawn.

Claim Rejections under 35 U.S.C. §103

The Office Action further rejects claims 6 and 8 under 35 U.S.C. §103(a) as being unpatentable over Gertzman.

Claim 6 is ultimately dependent upon claim 1. Applicant believes that independent claim 1 is allowable for the reasons discussed above. Accordingly, Applicants believe that dependent claim 6 should be allowed as well. Concerning claim 8, this claim has been amended in a manner similar to claim 1. Particularly, the concentration of bone particulate is recited as being of at least 50% by weight. The teachings in Gertzman are addressed above. Applicants believe that amended claim 8 should be allowable over Gertzman for the same reasons that amended claim 1 is allowable.

Lastly, the Office Action rejects claims 1-14 and 19 under 35 U.S.C. §103(a) as being unpatentable over Gertzman in view of Tofe, US Patent Application Publication No. US2003/0143283 ("Tofe"). It is respectfully submitted that the presently claimed invention, as recited in amended claims 1-14 and 19, is not prima facie obvious over the disclosures in Gertzman and Tofe for the reasons discussed below.

The Gertzman reference is discussed above, and these points will not be repeated for the sake of brevity. It is believed that amended claims 1-14 and 19 are patentable over Gertzman. Turning to Tofe, this reference refers to a bone repair composition comprising non-human bone material such as granulated or powdered bovine or other animal bone suspended in a hydrogel carrier such as high molecular weight hyaluronate. Tofe readily admits that the Gertzman material can be used in the Tofe bone repair composition (See Paragraph 0013). Tofe merely adds that his composition may further contain a polypeptide sequence as described in the Bhatnagar patents to help promote bone growth. However, there is nothing in the disclosure of Tofe which suggests how to add the polypeptide sequences to the composition. Tofe fails to teach whether the polypeptide sequences are irreversibly bound to the bone particulate or if they are added unattached. Meanwhile, in the present invention, as recited in the amended claims, the polypeptide sequences are bound to the particulate. This is significant, because the bound particulate helps induce bone growth. Secondly, there is nothing in Tofe suggesting the concentration of bone particulate, carrier material, or polypeptide sequences in the composition. There is no information provided about the molecular weights or densities of the components. Tofe is completely silent as to these points. Moreover, there is no teaching or any examples describing how to mix or formulate the composition. Tofe simply refers to the general disclosures in the Gertzman and Bhatnagar patents.

Thus, even if a person of ordinary skill in the art looked to the disclosure in Tofe and combined it with the teachings in Gertzman, the present invention still would not be

obvious. Accordingly, it is respectfully requested that the rejection of claims 1-14 and 19 under 35 U.S.C. §103(a) over Tofe and Gertzman be withdrawn.

Conclusion

In summary, Applicants submit that claims 1-14 and 19 (as amended) are patentable and each of the Examiner's rejections and objections has been overcome. Accordingly, Applicants request favorable consideration and allowance of amended claims 1-14 and 19. The Commissioner is hereby authorized to charge any additional fee required in connection with the filing of this paper or credit any overpayment to Deposit Account No. 04-0780. Should there be any outstanding matter that needs to be resolved in the present application; the Examiner is invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,
DENTSPLY International Inc.

By: Daniel W. Sullivan
Daniel W. Sullivan
Reg. No.: 34,937
Tel.: (717) 849-4472
Fax: (717) 849-4360

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Attachments: Petition for Extension of Time